

### DETAILED ACTION

This action replaces the non-final action dated 12-20-11.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-20-10 has been entered.

In response to the amendment dated 10-19-09 and the interview dated 2-16-11, the previous rejection of record has been withdrawn and the following new rejection has been applied:

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 8-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,268,176 to Znaiden et al as evidenced by James et al. (Radiographic, 1999, pages 1093-1099).
3. Znaiden patents teach topical preparations comprising phytic acid in the amounts of 5-50% or at least 3% (176 patent, examples, claims 3-4 and col. 3, l 27-41). Znaiden reference ('176) teaches the penetration of the compound through the skin layers (col.3, l 1-11). While Znaiden 176 patent teaches the composition for topical treatment of spider veins (telangiectasia or spider veins- see abstract and col. 1-2), and not the claimed method of treating tissue calcification, James (Radiographics) teaches the

occurrence of soft tissue calcifications in patients with varicose veins (see page 1093 col. 1-2, History and Findings). This is further described on page 1095, col. 1. Instant claims are not limited to any specific patient population and hence may include patient population with varicose veins. "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

2. Applicants previously argued the rejection of instant method claims over the above Znaiden patent (**page 6 of the remarks of 2/5/08**). However, in the present rejection, the examiner provided evidence that varicose veins and soft tissue calcification can coexist in patients and instant claims do not exclude such population. Applicants previously argued that the above reference teaches phytate for being sequestered in the skin layers as a depot, whereas "[s]urprisingly, the inventors of this invention have found that phytate, with a high negative charge, can be absorbed by the skin when it is administered topically, passing through into the bloodstream and acting on the damaged zone (in which a heterogeneous nucleant would have been generated)." Applicants submit that Znaiden does not teach a method of treatment or prevention wherein the phytate is absorbed through the skin into the bloodstream, as disclosed in new Claims 8- 19, and does not disclose every element of the claims,

Applicants respectfully request the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(b).

3. Instant claims recite the composition only with myo-inositol hexaphosphate or its salts and do not recite any formulation. Therefore, if applicants if the same compound of the prior art (by virtue of its chemical properties) does not penetrate through skin layers for absorption, then for the same reason instant compound also should fail to penetrate. However, Znaiden while teaching that the compound is sequestered in the skin layers, Znaiden also teaches a "formulation" containing the compound, which can enable its penetration and absorption. In this regard, if applicants' "unexpected absorption" (which is otherwise not possible with the compound based on Znaidens' teaching) is due to the presence of other penetration and/or absorption enhancers in the claimed composition, then the examiner notes that instant claims are silent regarding such penetration and absorption aids and absent such the composition of Znaiden reads on the instant composition. Products of identical chemical composition cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

If applicants argue that the claimed method is not inherent to Znaiden et al ('176 patent), then the following rejection based on obviousness is applied:

***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 8-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of US 5,552,148 or US 5,268,176 both to Znaiden et al, in view of Horrobin et al. (US patent 5,516,801), and Kamiya et al. (US Patent Application Pub. No. 2003/0119910), and further in view of James et al. (Radiographics, 1999, pages 1093-1099).
6. Znaiden patents teach topical preparations comprising phytic acid in the amounts of 5-50% or at least 3% (176 patent, examples, claims 3-4 and col. 3, l 27-41) or '148 patent teaches 0.001% to 40% or preferably 0.5%-10% (col. 2, l 38-52 and examples). While Znaiden 176 patent teaches the composition for topical treatment of spider veins (telangiectasia or spider veins- see abstract and col. 1-2), and '148 as a cosmetic additive, neither teach the claimed method of treating tissue calcification. However, 148 suggest the compound for various therapeutic methods (see col. 1) such as spider veins, acne etc.
7. While instant claims require topical administration of phytic acid, the claims do not recite the actual amount and further only states "pathological calcification treating

effective amounts" of phytic acid. The examples in the instant specification recite 2.9%; 0.7% and 2.5% (pages 7-9) for topical application.

8. Kamiya et al. teach methods of treating or preventing aging-associated diseases caused by a decrease in the expression of Klotho protein in animals or humans, including aging, ectopic calcification, skin involution, arteriosclerosis, hyperlipidemia, hypertension, cerebral apoplexy, diabetes, senile dementia of Alzheimer type (para 0022-0023). In particular, Kamiya et al. teach compositions comprising phosphorus containing compounds, such as phytic acid, for treating said diseases in animals or humans (abstract; para. 0081). Also, Kamiya et al. disclose that it is desirable to administer said compositions by any desirable route that is most effective for the treatment, including non-oral routes (para. 0044). Kamiya teaches an amount of 0.5% to 5% or more per unit dry weight of food or feed drink.

9. James (Radiographics) teaches the occurrence of soft tissue calcifications in patients with varicose veins (see page 1093 col. 1-2, History and Findings). This is further described on page 1095, col. 1.

10. Horrobin et al. is added as an evidentiary reference to show that ectopic calcifications involve various soft tissues, including blood vessels, kidney, skin, and brain (col. 2, lines 14-32).

11. Thus, one of an ordinary skill in the art would have been able to employ the topical compositions comprising phytic acid of Znaiden references for treating varicose veins and still expect to achieve a therapeutically effective treatment for soft tissue

calcification because James et al teach that the patients with varicose veins also exhibit soft tissue thickening and calcification and further because Kamiya teaches treating or preventing aging-associated diseases caused by a decrease in the expression of Klotho protein in animals or humans, including aging, ectopic calcification, by administering phytic acid. This is further true because instant claims do not exclude the patient populations with varicose veins (Znaiden) or other age related problems other than ectopic calcification (Kamiya).

12. Instant claims recite the composition only with myo-inositol hexaphosphate or its salts and do not recite any formulation. Therefore, if applicants if the same compound of the prior art (by virtue of its chemical properties) does not penetrate through skin layers for absorption, then for the same reason instant compound also should fail to penetrate. However, Znaiden while teaching that the compound is sequestered in the skin layers, Znaiden also teaches a "formulation" containing the compound, which can enable its penetration and absorption. In this regard, if applicants' "unexpected absorption" (which is otherwise not possible with the compound based on Znaidens' teaching) is due to the presence of other penetration and/or absorption enhancers in the claimed composition, then the examiner notes that instant claims are silent regarding such penetration and absorption aids and absent such the composition of Znaiden reads on the instant composition. Products of identical chemical composition cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d

1655, 1658 (Fed. Cir. 1990). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

13. Further, one would reasonably expect that the topical administration/application to the skin of a composition comprising the instantly claimed myo-inositol hexaphosphate (phytic acid) as taught by Znaiden or Kamiya et al. would be absorbed by the skin and then travel via the bloodstream to the target site where the calcification is generated, including the sub epithelial tissue, renal tissue, pulmonary tissue, cerebral tissue, and the wall of a blood vessel because Kamiya et al. and Znaiden references teach therapeutically effective compositions containing phytic acid. Besides, Kamiya et al. teach compositions for treating aging-associated conditions (e.g. skin wrinkles), which overlaps with the instant claimed population (i.e. ectopic calcification) as evidenced by the teaching of Kamiya et al. and Horrobin et al.

14. With respect to the preamble of claim 14, it is noted that Kamiya et al. teach methods for preventing aging-associated diseases, including ectopic calcification, comprising administering compositions comprising phytic acid (para. 0081). A skilled artisan would have expected to prevent the development of calcification from the teachings of Znaiden, for the reasons mentioned above.

15. With respect to the limitations recited in dependent claims 9-13 and 15-19, it is noted that Kamiya et al. teach aging-associated diseases including ectopic calcification, which overlaps with the instant claimed population (pathological calcification in a soft

tissue). Since ectopic calcification involves soft tissues, including skin, brain, kidney, and blood vessels, one would reasonably expect that the method of treatment comprising topically administering the same instantly claimed compound as taught by the prior art would also be effective in treating/ preventing pathological calcification involving sub epithelial tissue, renal tissue, pulmonary tissue, cerebral tissue, and the wall of a blood vessel as evidenced by the teaching of Horrobin et al. (col. 2, lines 14-32).

#### ***Response to Arguments***

4. Applicant's arguments, filed 10-19-09, with respect to the rejection(s) of claim(s) as being obvious over Kamiya et al in view of Horrobin and Bissett et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as above. Further, as mentioned in the attached interview summary, the examiner admitted that the rejection of 12/20/10 will be withdrawn because of the inadvertent use of Grases publication that is published after the priority date of the instant application and hence does not constitute prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKSHMI CHANNAVAJJALA whose telephone number is (571)272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone



number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/  
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